MAR - 5 2001

Summary of Safety & Effectiveness
Vigil™ Serology Control Level C
K 010358

1.0 **Submitted By:**

Annette Hellie
Principal Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 993-8767
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2.0 **Date Submitted:**

February 5, 2001

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Vigil® Serology Control Level C

3.2 **Classification Name**

Quality control material (assayed and unassayed)
(21 CFR § 862.1660)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
Vigil Serology Control Level C	Vigil Serology Controls (Level 1)	Beckman Coulter, Inc.	K930850

5.0 **Description:**

Vigil™ Serology Level C stabilized liquid-control is designed for monitoring the overall performance of Anti-Streptolysin O, Rheumatoid Factor, and C-Reactive Protein test systems in the Clinical laboratory.

6.0 Intended Use:

Vigil™ Serology stabilized liquid-control is designed for monitoring the overall performance of Anti-Streptolysin O, Rheumatoid Factor, and C-Reactive Protein test systems in the Clinical laboratory. The use of three levels of control enables the laboratorian to monitor changes in the calibration along with analytical error and imprecision. Vigil Serology is not intended for use as a standard.

Clinical Significance:
A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls.

7.0 Comparison to Predicate(s):

The Vigil Serology Control Level C matrix is identical to the current Vigil Serology Control Level 1. The only difference is the reduced level of the C-reactive protein analyte.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stress stability studies of the Vigil Serology Control Level C support the Beckman Coulter stability claim of 24 months.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 5 2001

Ms. Annette Hellie
Principal Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Brea, California 92822-8000

Re: K010358
Trade Name: Vigil™ Serology Control Level C
Regulatory Class: I
Product Code: JJY
Dated: February 5, 2001
Received: February 6, 2001

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010358

Device Name: **Vigil™ Serology Control Level C**

Indications for Use:

Vigil™ Serology stabilized liquid-control is designed for monitoring the overall performance of Anti-Streptolysin O, Rheumatoid Factor, and C-Reactive Protein test systems in the Clinical laboratory. The use of three levels of control enables the laboratorian to monitor changes in the calibration along with analytical error and imprecision. Vigil Serology is not intended for use as a standard.

862.1660 Quality control material (assayed and unassayed).

Identification. A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Joseph L. Hackett

Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Clinical Laboratory Devices

510(k) Number

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96